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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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WASHINGTON, DC 20004-1206

EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

25

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/404,520

Applicant(s)

CAO ET AL.

Examin r

T Strzelecka

Art Unit

1637

-- The MAILING DATE of this c mmunication app ars on the c ver sheet with the correspondence address --

P ri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 28, 2002 & October 28, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 24.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____.

DETAILED ACTION

Applicant's Petition filed under 37 CFR §1.181 (August 28, 2002 (Paper No: 21)) has been treated as a request for reconsideration of the Group Director's decision (Paper No: 17, July 10, 2002) on applicant's petition of March 27, 2002 (Paper No: 16). This decision concerns only those claims currently pending and will address only the issues pertinent thereto. The currently pending claims are directed toward analysis of sequence information wherein the sequence information resides in specifically recited SEQ ID No:s. The examiner had required applicant to elect a single sequence. In the decision of July 10, 2002 the Group Director had affirmed the examiner's position. However, upon review the prior affirmance is VACATED.

Applicant's pending claims are directed to the manipulation of strings of information which information is non-functional descriptive material. Non-functional descriptive material cannot form the basis for non-obviousness or patentability. Because the SEQ ID NO:s in the now pending claims are information they will not be searched and no restriction to a single elected sequence required.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 28, 2002 has been entered.
2. This office action is in response to an amendment filed on October 23, 2001. Claims 57 and 58 were pending. Applicants amended claims 57 and 58.
3. In an amendment filed on October 28, 2002, Applicants amended the title of the invention. Amendment has been entered.
4. This office action contains new grounds of rejection for claims 57 and 58.

Specification

5. On page 52, lines 6 and 7, there are two sequences without SEQ ID NOs. If these sequences are already present in the submitted CRF and paper sequence listing, SEQ ID NOs

should be added next to the sequences. If these sequences are not present in the submitted CRF and paper sequence listing, new CRF and a paper copy of sequence listing should be submitted.

Claim Rejections - 35 USC § 101 Utility

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. The pending claims have been reviewed in light of the the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, □ Written Description □ Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

8. Claims 57 and 58 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

9. Claim 57 is drawn to a computer based system comprising a computer readable medium having recorded thereon at least 100 nucleotide sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof. Claim 58 is drawn to a method of identifying a nucleotide sequence comprising comparing target sequence to a sequence stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof.

Patentability of these claims is based on a computer readable medium with at least 100 nucleic acid sequences recoded thereon. These sequences were obtained from a genome of *Emericella Nidulans*. However, there is no indication in the specification of what are the functions of any of the sequences with SEQ ID NO: 16207-27905. The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to any sequence data recorded on computer readable medium. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. For example, if these at least 100 sequences were used in the method of claim 58 for comparison with sequences of known function, this would constitute further characterization of these at least 100 sequences. Comparison of these at least 100 sequences with other unknown sequences would also lead to further investigation of their properties.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

10. Claims 57 and 58 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a

well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claims 57 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed, including the originally filed claims, for the specific selection of the 100 sequences in the pending claims.

Remarks concerning the art rejection

11. The following is used as a basis for the rejection of claims 57 and 58.

MPEP 2106. IV.B.1(b)

(b) Nonfunctional Descriptive Material

Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C.101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided. Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such “descriptive material” is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).) The policy that precludes the patenting of nonfunctional

descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an article of manufacture. For example, music is commonly sold to consumers in the format of a compact disc. In such cases, the known compact disc acts as nothing more than a carrier for nonfunctional descriptive material. The purely nonfunctional descriptive material cannot alone provide the practical application for the manufacture.

MPEP 2106.VI Patentable Subject Matter — Computer-Related Inventions

If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in paragraphs IV.B.1(a) and IV. B.1(b). Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. In re Dembiczak, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999). Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

12. Sequences stored on a computer readable medium are therefore considered as non-functional descriptive material.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez-Tome et al. (Nucl. Acids Res., vol. 24, pp. 6-12, 1996).

Regarding claim 57, Rodriguez-Tome et al. teach CD-ROM with containing EMBL nucleotide sequence database (page 6, second paragraph). Rodriguez-Tome et al. do not specifically teach a computer system comprising input means for receiving a target sequence. However, such means constitute computer with a keyboard and display, the possession of which is inherent in using the CD-ROM. Rodriguez-Tome et al. teach that the CD-ROM also contains software for data query and retrieval (=means for identifying fragments of sequence which are homologous to a target sequence and output means for outputting identified computer sequence (page 9, the last paragraph; page 10, first paragraph).

Regarding claim 58, Rodriguez-Tome et al. teach comparing users' sequences (= target sequences) to sequence in the EMBL nucleotide sequence database (page 10, paragraph 8).

It would have been *prima facie* to obvious for one of ordinary skill in the art to have used a computer system comprising a CD-ROM of Rodriguez-Tome et al. to perform sequence searches against a collection of sequence data. The motivation to do so would have been that using CD-ROM made database searches accessible to clients without Internet access.

15. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Michael P. Woodward

SPE AU 1631



John J. Doll

Director TC 1600